

Inspection Findings and Follow-up Actions

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Objectives

- Inspection Results
- Follow-Up Actions

Recent Inspection Results

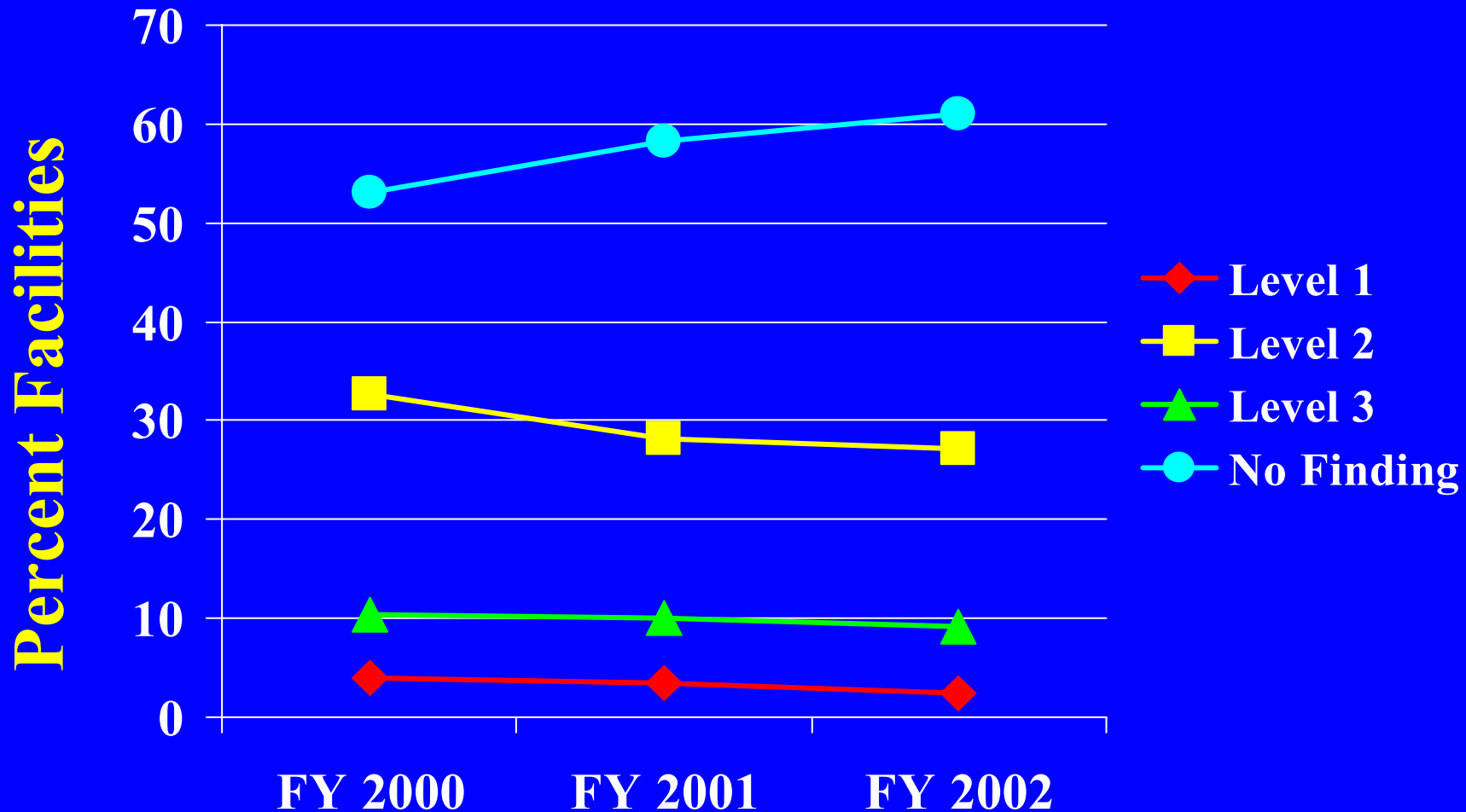
Fiscal Years 2000 to 2002*

*10/1/2001 to present

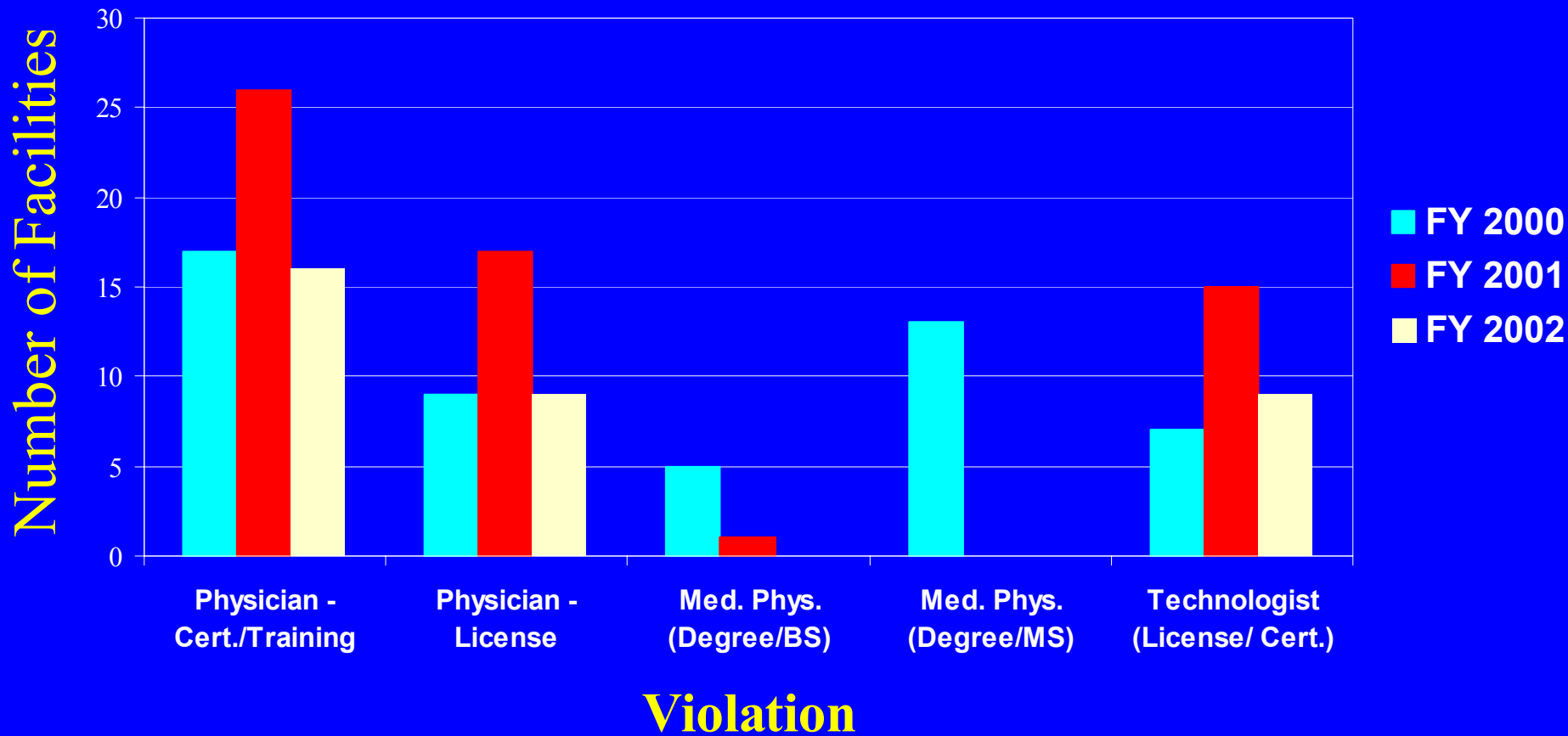
Inspection Finding Levels

- Level 1 - Serious
- Level 2 - Moderate
- Level 3 - Minor

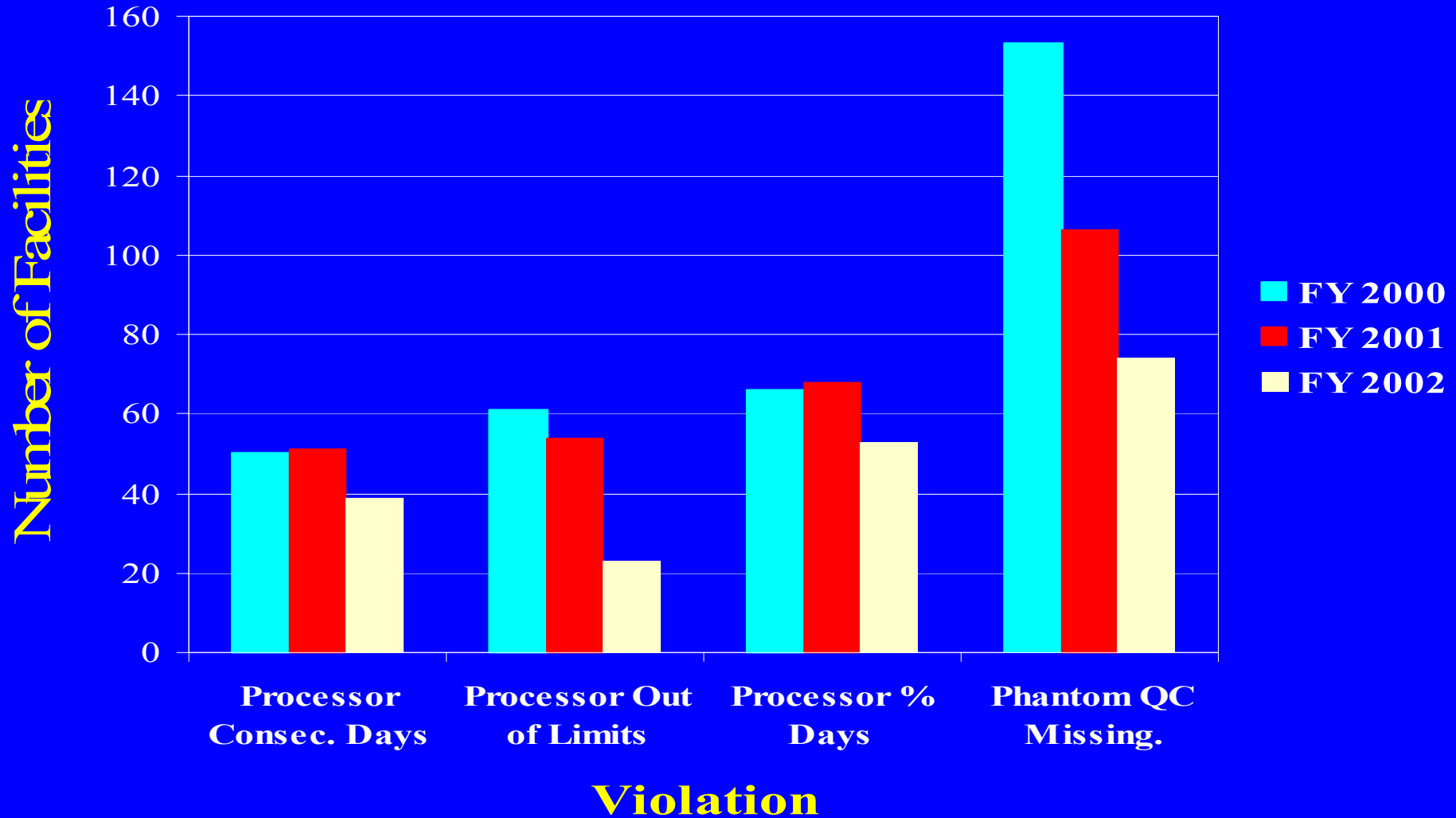
Violations by Level Change by Year



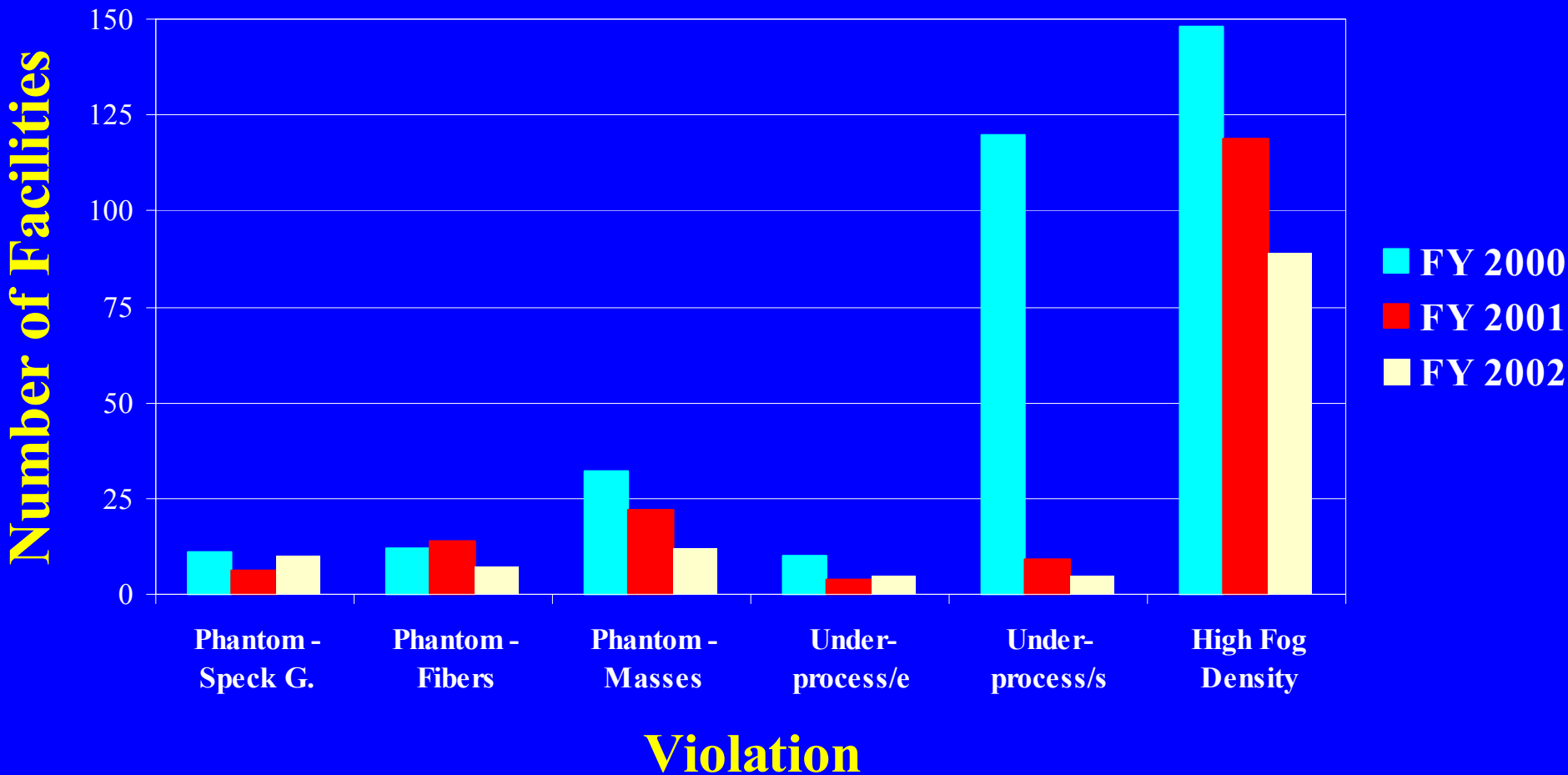
Level 1 Initial Qualifications



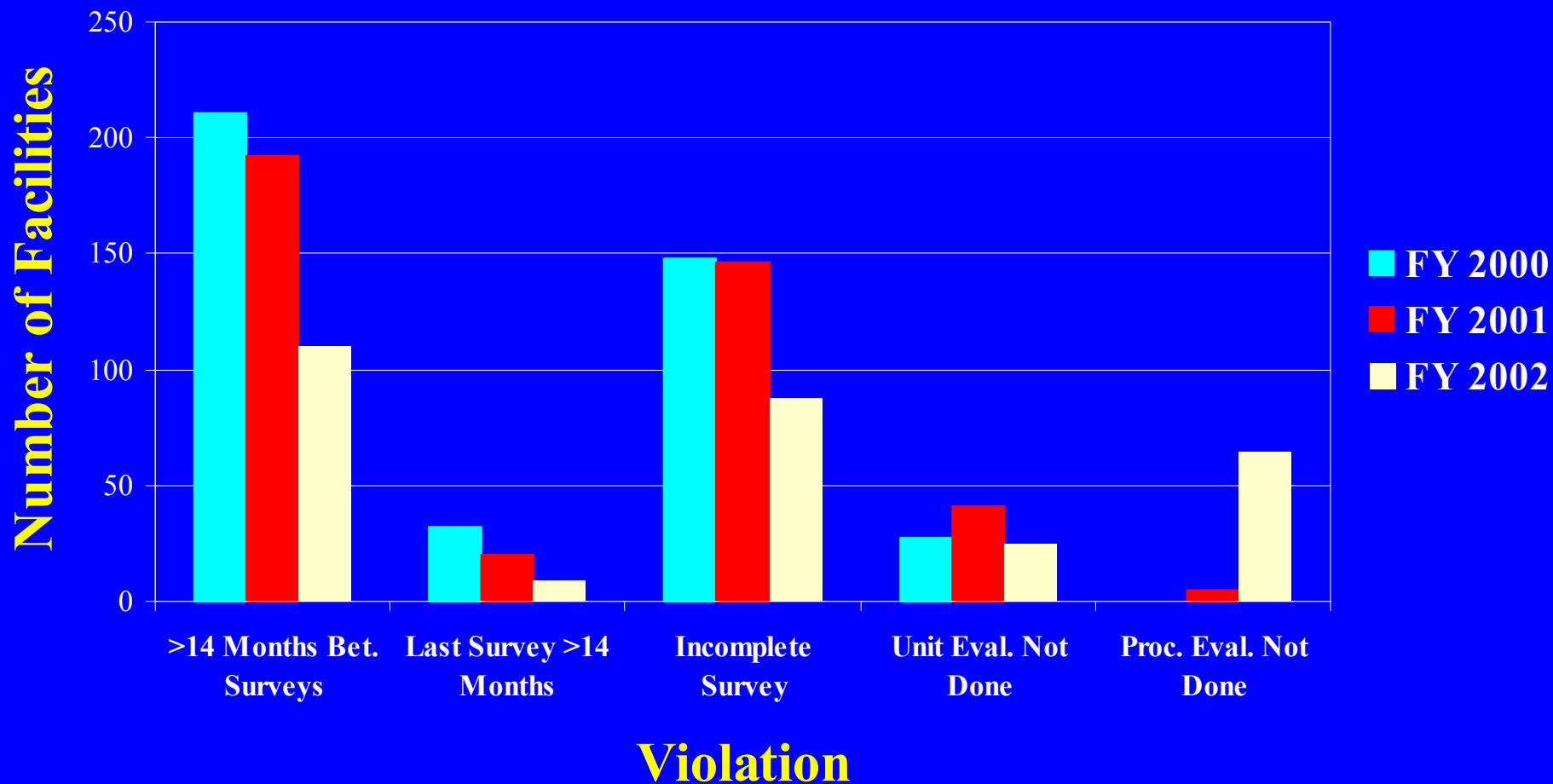
Level 1 Processor and Phantom Quality Control



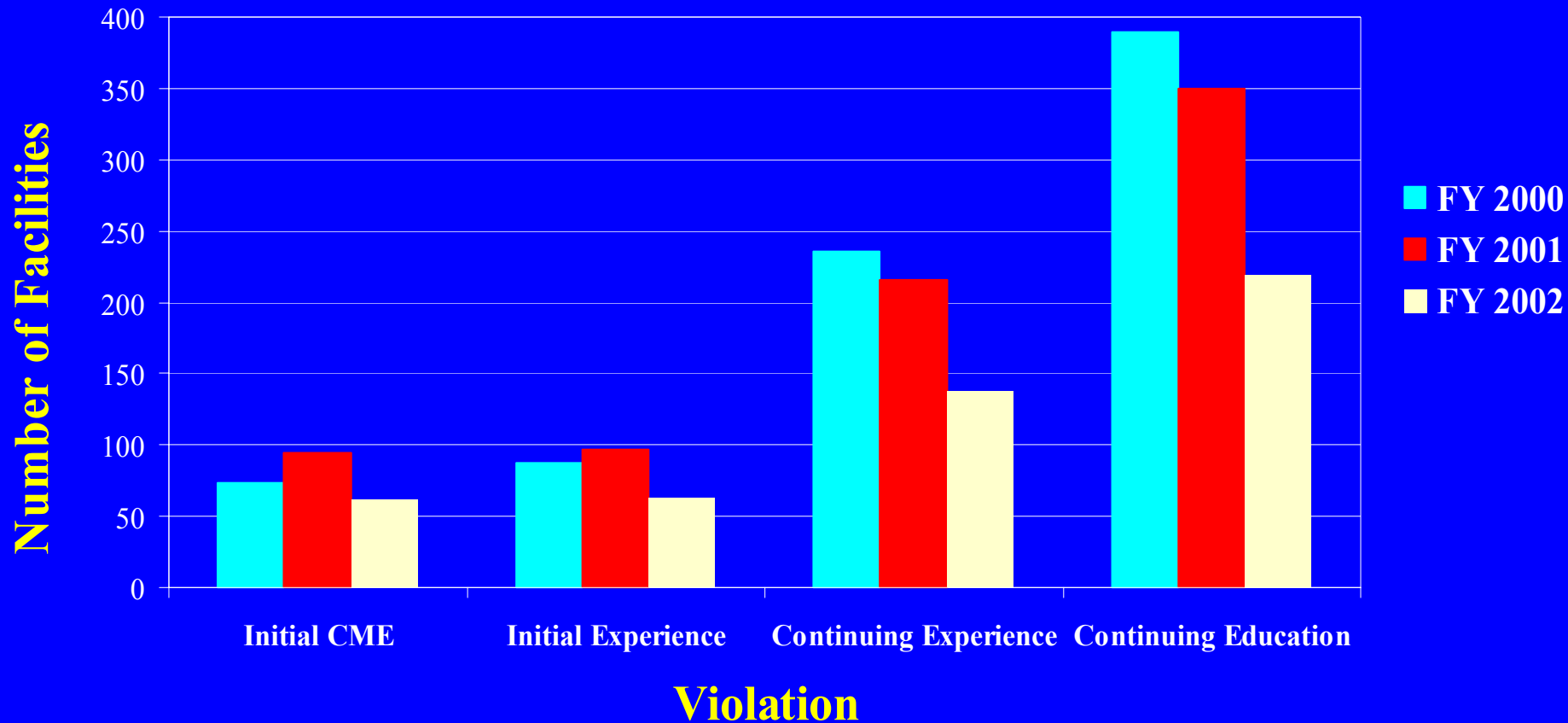
Level 2 Phantom Score & Processing Conditions



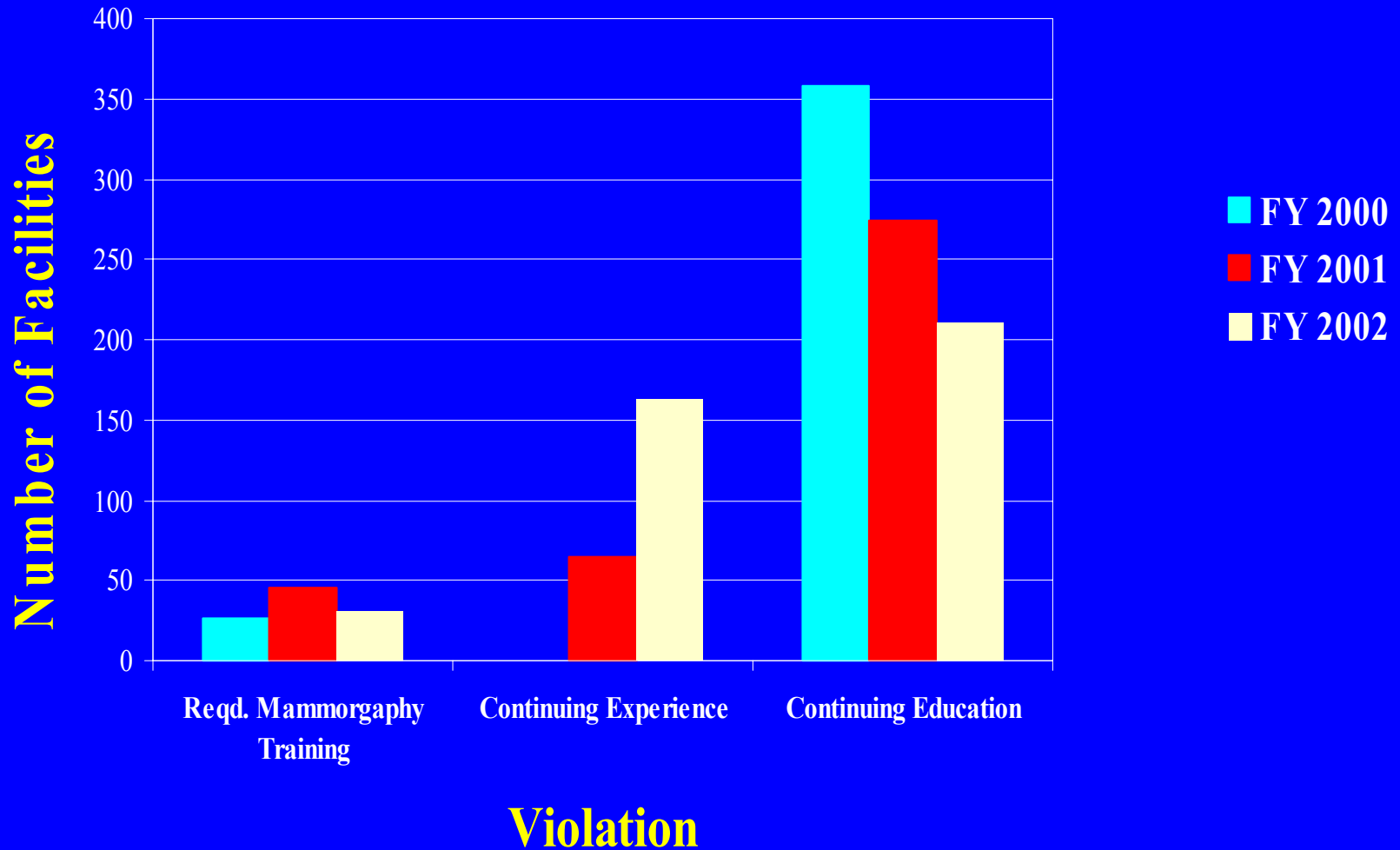
Level 2 Annual Survey & Equipment Evaluation



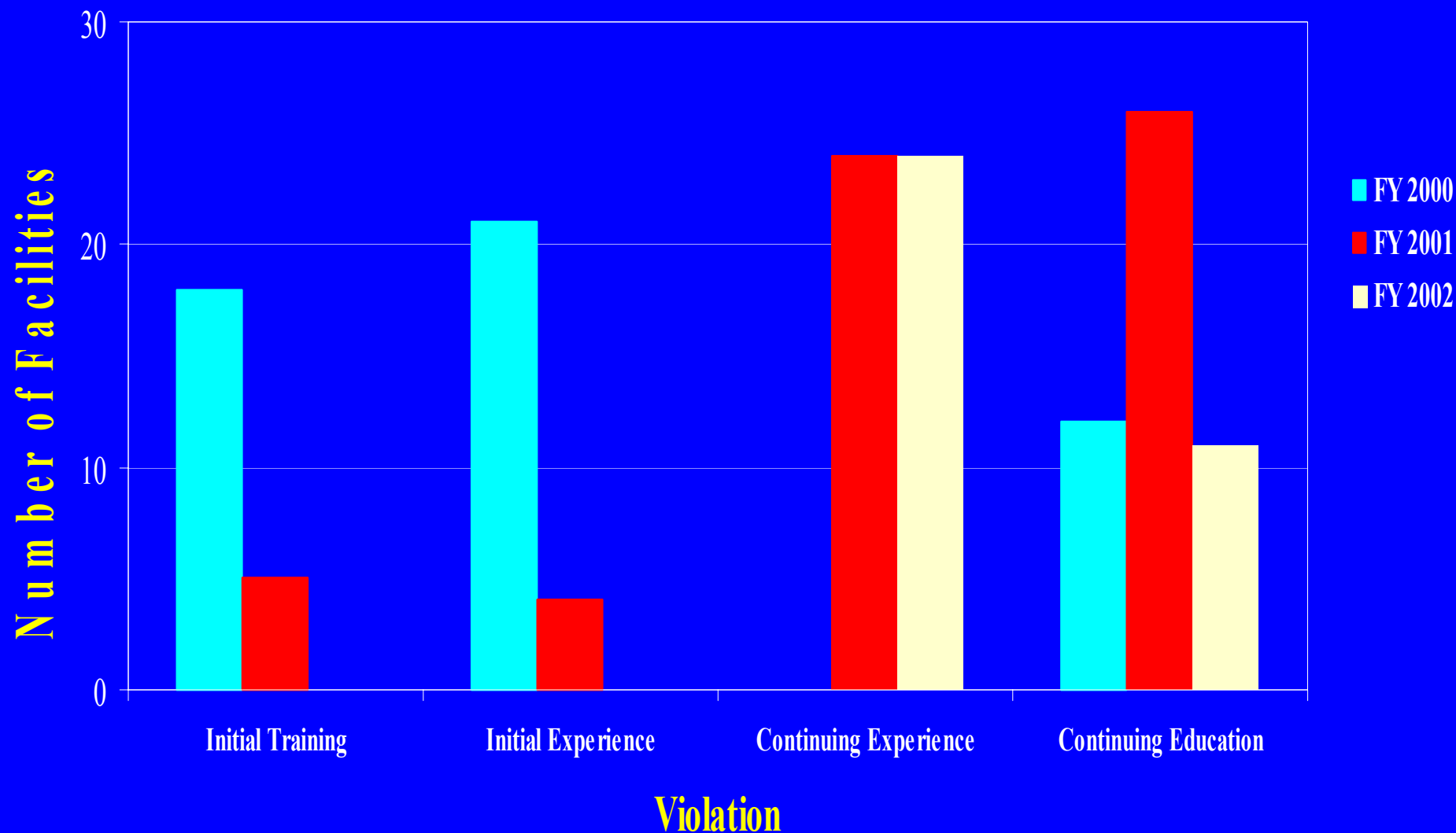
Level 2 Interpreting Physician Qualifications



Level 2 Technologist Qualifications

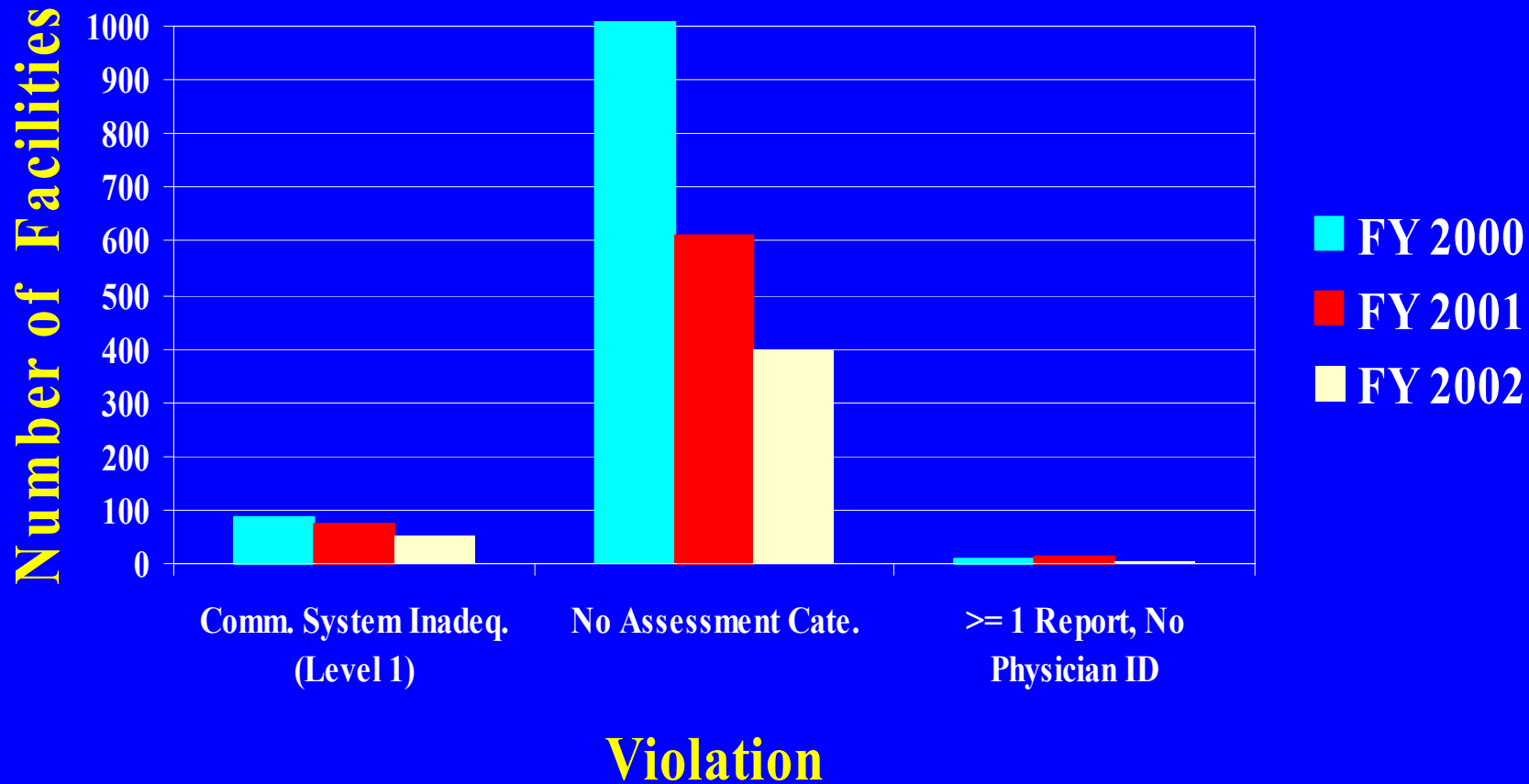


Level 2 Medical Physicist Qualifications

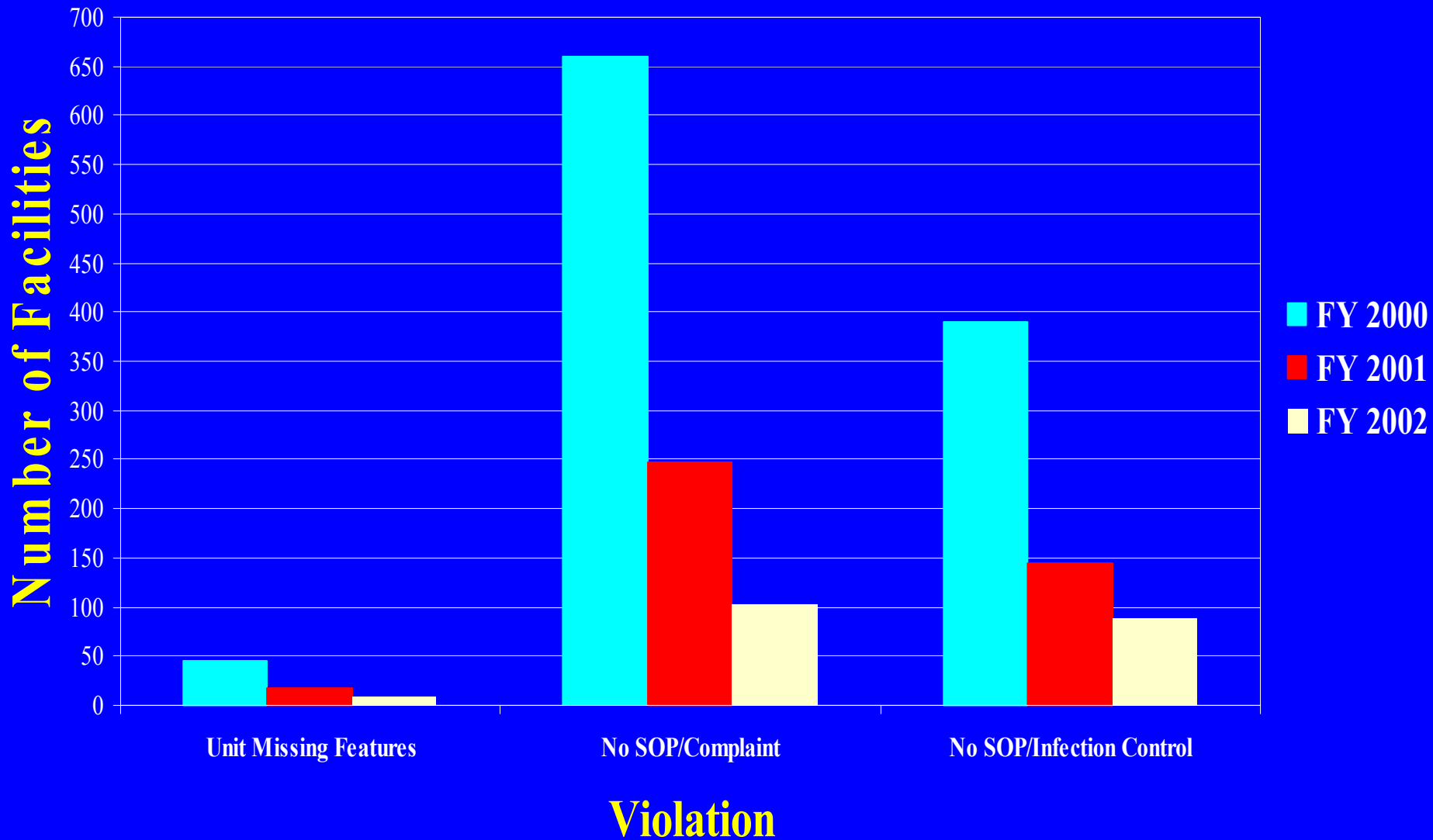


Medical Records Issues

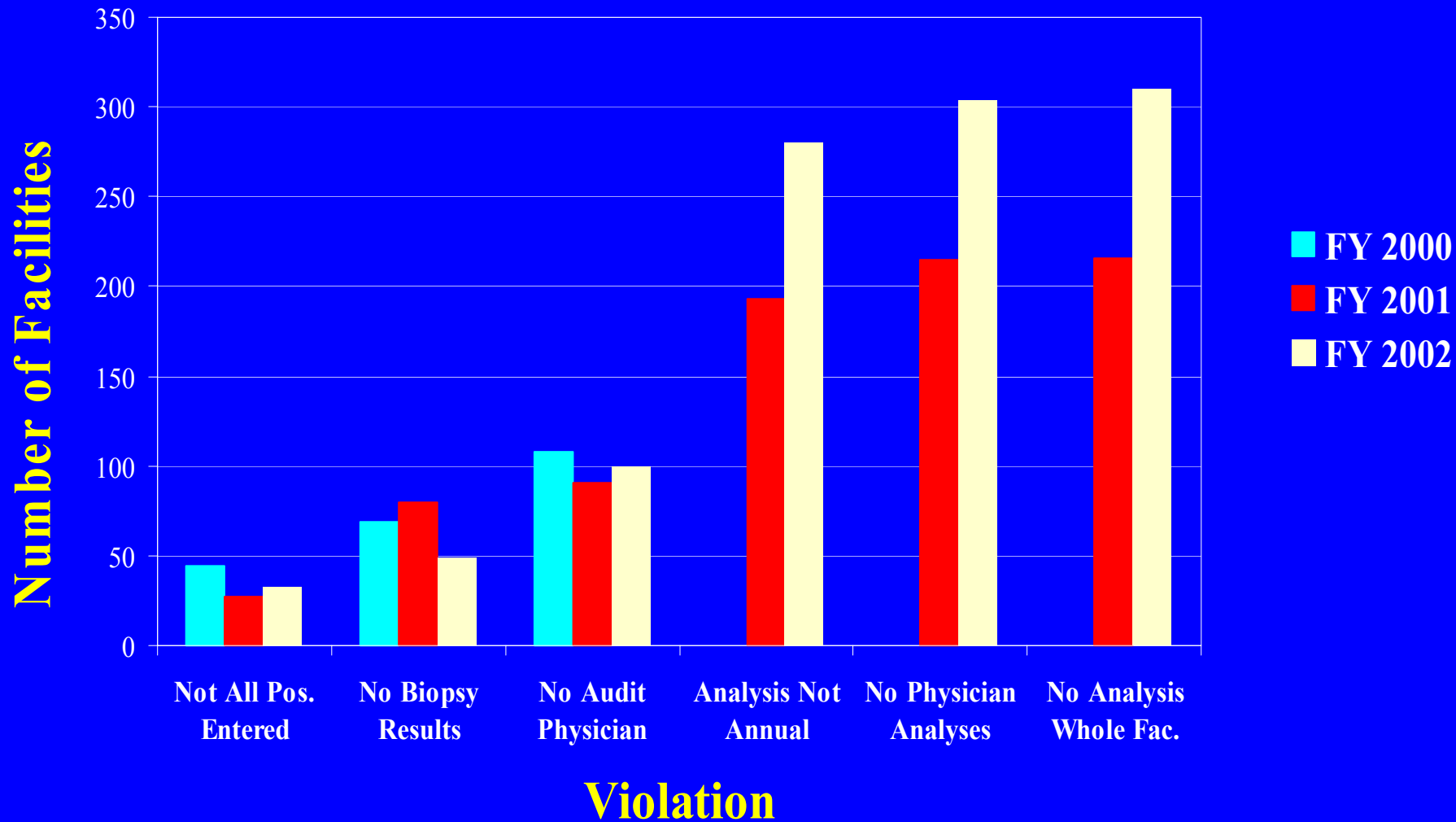
Levels 1 and 2



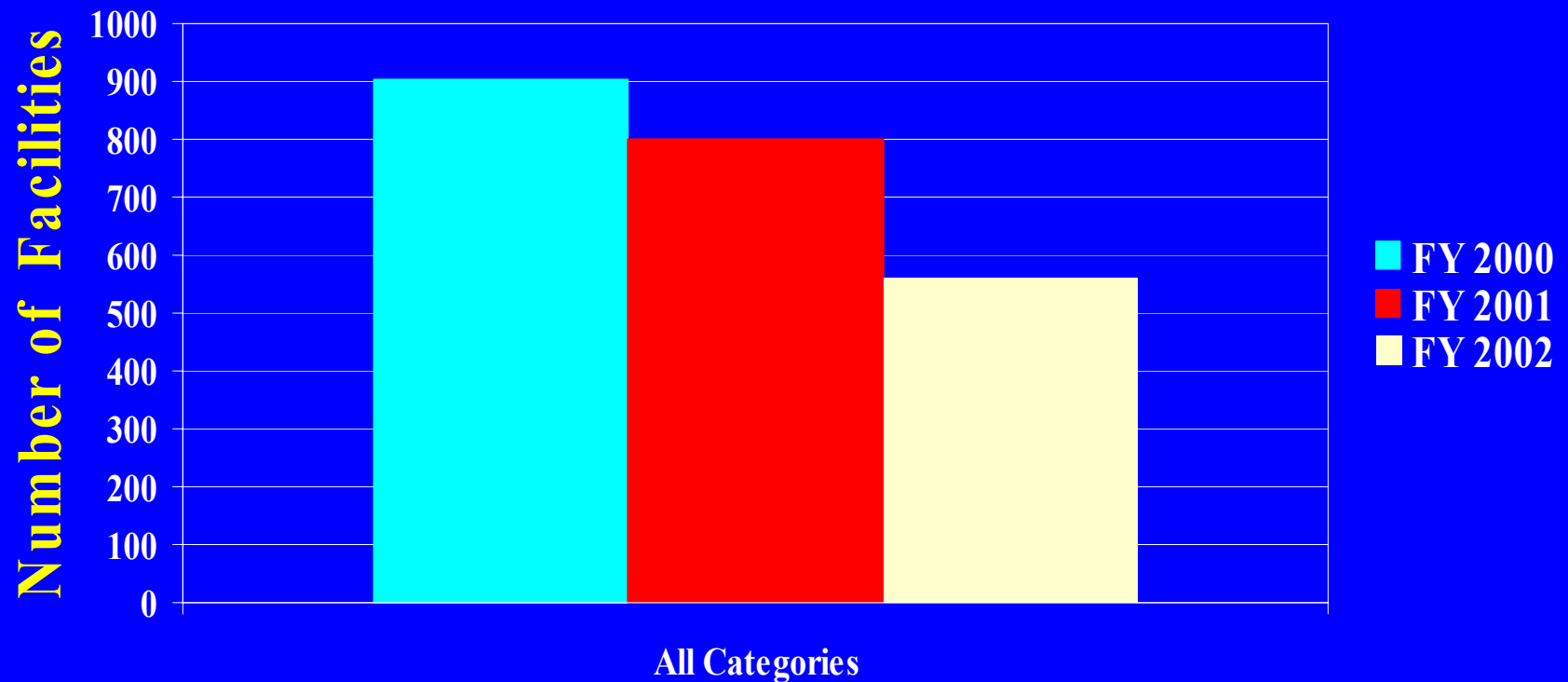
Level 2 Unit Requirements and QA Issues



Level 2 Audit System



Level 3 Failure to Maintain Required Personnel Documents



Follow-Up Actions

Types of Actions

- **Follow-Up Inspections**
- **Additional Mammography Review**
- **Patient and Physician Notification**
- **Directed Plans of Correction**
- **Civil Money Penalties**
- **Suspension or Revocation (of certificate)**
- **Injunction**

Follow-Up Inspection

- **Check on corrective actions for serious problems (Level 1)**
- **Usually limited to specific problems**

Additional Mammography Review

- **Review by Accreditation Body or other party**
- **Possible patient and physician notification (serious risk)**

Additional Mammography Review

- **Level 1 phantom image (inspection)**
- **Level 1 interpreting physician**
- **Clinical image quality problems**
- **Overall quality assurance failures**
- **Fraudulent recordkeeping**

Additional Mammography Review

- **Limited AMR (phantom image)**
- **Full AMR**
 - **Fail limited AMR fail (serious risk to health)**
 - **Substantial facility problems**

Patient and Physician Notification

- **AMR shows serious risk to health**
- **Provides patients and physicians with follow-up options**
- **Plain language used**

Directed Plans of Correction

- **Imposes additional requirements on facility**
- **Monitoring of quality assurance program**
- **Additional inspections**

Suspension

- **Serious violations**
- **Voluntary corrections ineffective**
- **Health Hazard – no prior hearing**

Other Sanctions

- **Civil Money Penalties (up to \$10,000 per violation)**
- **Revocation of certificate (two year prohibition for owner/operator)**
- **Injunction – closes facility**

Action	Number
Additional Mammography Reviews	35
Patient and Physician Notifications	11
Directed Plans of Correction	3
Civil Money Penalties	1
Suspensions	1
Revocations, Injunctions	0